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| 09/494,149 | 01/28/2000 | Spencer R. Malecha | A-67641-1/RPT/DSS | 3091 |

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EXAMINER

PARAS JR, PETER

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1632

DATE MAILED: 06/13/2003

25

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicant(s)

09/494,149

Applicant(s)

MALECHA ET AL.

Examiner

Peter Paras, Jr.

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- The MAILING DATE of this communication appears on the cover sheet with the correspondence address -

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.138(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 March 2003.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 29 March 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

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Applicant's amendment received on 3/28/03 has been entered. Claims 1, 3, 6 and 10-11 have been amended. Claims 1-11 are pending and are under current consideration.

Drawings

The drawings filed on 3/28/03 are approved by the Examiner.

Sequence Compliance

The sequence listing in computer readable and paper forms has been entered. The instant application is now in sequence compliance.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 10-11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The previous rejection is maintained for the reasons of record advanced on pages 3-4 of the Office action mailed on 8/6/02.

Applicant's arguments filed 3/28/03 have been fully considered but they are not persuasive. Applicants have argued that the prawn populations recited in the claims are not found in nature. In particular, Applicants assert that the female to male ratios, wherein the percentage of females is greater than 90% is substantially greater than the percentage of females present in wild-type populations. Applicants point out that the

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collecting and sexing of shrimp and prawns, in contrast to the Examiner's assertions are artificial processes, which do not occur in nature. See pages 8-9 of the amendment.

In response, the Examiner maintains that the claims are product by process claims, in which the process carries little patentable weight because the product does not recite any distinguishing features as a result of carrying out the claimed method. See *In re Thorpe* on page 3 of the Office action mailed on 8/6/02. It is maintained that the claims are interpreted as being directed to a population of normal shrimp or prawns, wherein the shrimp or prawns embraced by the claims are phenotypically and genetically normal. Moreover, the process of breeding a neomale shrimp with a normal female does not produce progeny that are different from other wild-type shrimp or prawns. The Examiner agrees that collecting and sexing shrimp or prawns does not occur in nature, however such would result in a population of shrimp or prawns that anticipates the instant claims; for example a population of exclusively female shrimp in a tank would anticipate that instant claims.

Accordingly, the rejection is maintained for the reasons of record and as discussed above.

Claim Rejections - 35 USC § 112, 1st paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 3-5 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The previous rejection is maintained for the reasons of record advanced on pages 5-8 of the Office action mailed on 8/6/02.

Applicant's arguments filed on 3/28/03 have been fully considered but they are not persuasive. Applicants assert that the Examiner has not presented sufficient evidence or reasons for holding that the skilled artisan would not recognize a description of the instantly claimed invention as presented in Applicant's disclosure. Applicants have argued that the specification has described the isolation of male androgenic sex hormones from prawns and shrimp and methods of cloning the gene encoding the androgenic sex hormone. Applicants submit that the working examples presented in the instant specification show how to create neomale prawns and shrimp by contacting female prawns or shrimp with androgenic hormone. See pages 9-12 of the amendment.

In response, the Examiner maintains that the sequences of all the androgenic peptides within the genus of androgenic peptides have not been disclosed. The specification has disclosed isolation of an androgenic peptide from a single species of prawn (*Macrobrachium rosenbergii*) and from a single species of shrimp (*Panaeus vannemei*). See pages 5-6 of the Office action mailed on 8/6/02. The evidence of record however has not provided the amino acid sequence of any of the androgenic

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peptides embraced by the claims. As such, it is maintained that the evidence of record has not established a relationship between the structures of the androgenic peptides from the various shrimp and prawn species as well as from other animal species embraced by the claims. It is further maintained that the evidence of record has failed to describe the structural features that distinguish members of the genus of androgenic peptides from other peptides such that the skilled artisan would recognize that Applicants were in possession of the common attributes that identify members of the genus of androgenic peptides. As such it is maintained that Applicants were not in possession of the members of the genus of androgenic peptides embraced by the claims. See pages 7-8 of the Office action mailed on 8/6/02.

Accordingly, the rejection is maintained for the reasons of record and as discussed above.

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The previous rejection is maintained for the reasons of record advanced on pages 8-9 of the Office action mailed on 8/6/02.

Applicant's arguments filed on 3/28/03 have been fully considered but they are not persuasive. Applicants submit that the claims have been amended as per the

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Examiner's recommendations to overcome the rejection of record. See page 12 of the amendment.

In response, the Examiner asserts that the claims as amended still recite inconsistent language; the goal of the preamble is still not set forth in the steps of the claims. The preamble is directed to a method of producing a population of shrimp or prawns having a skewed percentage of females to males. The steps of the method however, have set forth that a population of shrimp or prawns is produced which has a skewed ratio of females to males. The Examiner asserts that a percentage is not the same as a ratio. As such it is maintained that the goal of the preamble does not relate to the steps of the method in a positive process. Claims 7-11 depend from claim 6. It is suggested that amending the claims such that the steps of the method result in a production of a population of shrimp or prawns having a skewed percentage of females to males may be sufficient to overcome the instant rejection and place claims 6-9 in condition for allowance. Claims 10-11 are subject to other rejections.

Accordingly, the rejection is maintained for the reasons of record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Malecha. The previous rejection is maintained with respect to claims 10-11 for the reasons of record advanced on pages 10-11 of the Office action mailed on 8/6/02. For clarity the rejection is reiterated below. The rejection over claims 1 and 3-5 has been withdrawn.

Malecha has taught that breeding neomale prawns with normal female prawns produces a population of progeny that is has a skewed percentage of females to males; in some cases Malecha reports that the percentage of females to males was greater than 90%. See page 211, Table 5, panel B, line 2, where it is reported that neomale 7 produced a sex-ratio of 1:22.18 (males to females), which is the equivalent of a population that is greater than 90% females to males, when backcrossed to normal females. Also see lines 3-5 of page 211 where Malecha reports that certain broods comprised sex ratios of zero: 1,809 and 1: 1,578, males to females, respectively. It is noted that claims 10-11 are product by process claims that are interpreted to read on a normal population of prawns because the method of making the prawns produced a population of normal prawns, the method not adding any distinguishing characteristics to the prawns. Patentability of a product-by-process claim is determined by the novelty and nonobviousness of the claimed product itself without consideration of the process for making it which is recited in the claims. *In re Thorpe*, 227 USPQ 964 (Fed. Cir. 1985).

In addition, as claims 10-11 are interpreted to read on a normal shrimp or prawn population having a skewed percentage of females to males, particularly greater than 90% female, it is of importance for the record to state that Malecha et al also teach three separate populations female prawns [that are different from the populations

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obtained from breeding neomale prawns as discussed above], wherein the populations do not comprise any male prawns. See page 203, the Material and Methods section, in the second full paragraph.

Thus, the teachings of Malecha meet all of the instant claim limitations.

Applicant's arguments filed 3/28/02 have been fully considered but they are not persuasive. Applicants have argued that Malecha has not taught neomale prawns, which do not contain transplanted androgenic gland tissue. As such Applicants assert that Malecha teaches away from the claimed invention. See pages 13-14 of the amendment.

In response, the Examiner asserts that the population of shrimp or prawns produced by the method does not differ from the populations of shrimp or prawns taught by Malecha. See above. The point raised by Applicants with respect to the neomale prawns of Malecha containing transplanted androgenic gland tissue is off point because the resultant progeny are not changed in any way by the method in which they are produced. A neomale prawn comprising transplanted androgenic gland tissue will produce the same progeny, having the same genotype and phenotype, as a neomale prawn that does not comprise transplanted androgenic gland tissue; the progeny in both situations are normal and do not differ from wild-type. As such the method of producing the populations of shrimp or prawns is not given consideration when determining the patentability of a claimed product. See *In re Thorpe* above. The evidence of record has not shown that neomale prawns produced by different methods will produce

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different progeny. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. In re Best, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. See the M.P.E.P. 2112.01.

Accordingly, the rejection is maintained with respect to claims 10-11 for the reasons of record and as discussed above.

Claims 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Nakashima. The previous rejection is maintained for the reasons of record advanced on pages 11-12 of the Office action mailed on 8/6/02.

Applicant's arguments filed 3/28/02 have been fully considered but they are not persuasive. Applicants have argued that Nakashima has not taught the breeding of a neomale shrimp or prawn with a corresponding female to produce a population of shrimp or prawn having a skewed percentage of female to males. Applicants further argue that the method of making the claimed populations produces a population, which contains a large number of female shrimp or prawns than the single shrimp of

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Nakashima. Applicants submit that a population comprises organisms located in a specified habitat from which a statistical can be obtained. As such Applicants are of the opinion that Nakashima does not anticipate the claimed invention.

In response, the Examiner asserts that the claims as written read on a normal population of shrimp or prawns. It is maintained that the method of making the population of shrimp or prawns embraced by the claims does not change the population in any way such that it can be distinguished from wild-type shrimp or prawns. See *In re Thorpe* on page 12 of the Office action mailed on 8/6/02. It is further maintained that the claims are properly interpreted to read on a normal population of shrimp or prawns. Where the claimed and prior art products are identical or substantially identical in structure or composition, or are produced by identical or substantially identical processes, a prima facie case of either anticipation or obviousness has been established. *In re Best*, 562 F.2d 1252, 1255, 195 USPQ 430, 433 (CCPA 1977). "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." *In re Spada*, 911 F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. *In re Best*, 562 F.2d at 1255, 195 USPQ at 433. See the M.P.E.P. 2112.01

It is maintained that the female shrimp of Nakashima represents a population of 1 female for a container. Since there are no male shrimp present, the population of shrimp in the container is 100% female. Applicant's arguments regarding the definition

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of the term population are off point for the following reasons: 1. The claim doesn't recite a habitat of the shrimp or prawns. It appears that Applicants are implying that the laboratory conditions where the claimed "populations" were produced are a habitat of shrimp or prawns; and 2. It is not known if the sample of the population of shrimp or prawns, embraced by the claims, measured to determine the percentage of females is statistically relevant.

Accordingly, the rejection is maintained for the reasons of record and as discussed above.

Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by EP 0514015A1. The previous rejection is maintained for the reasons of record advanced on pages 12-13 of the Office action mailed on 8/6/02.

Applicant's arguments filed 3/28/03 have been fully considered but they are not persuasive. Applicants have argued that EP 0514015A1 does not anticipate the claim because EP 0514015A1 does not teach a phenotypically male shellfish, which is sexually reproductive. Applicants assert that claim 2 requires the neomale shrimp or prawn to be sexually reproductive. See pages 15-16 of the amendment.

In response, the Examiner maintains that EP 0514015A1 anticipates the claimed invention. EP 0514015A1 has taught a shellfish which is genotypically female but is phenotypically male (which meets the definition of neomale provided by the instant specification) wherein shellfish are defined to encompass any crustacean, including shrimp and prawns. See pages 12-13 of the Office action mailed on 8/6/02. EP

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0514015A1 does not disclose that such shellfish are sexually reproductive but likewise does not disclose that such shellfish are not sexually reproductive. Furthermore, EP 0514015A1 does not disclose or suggest evidence allowing the ordinarily skilled artisan to conclude that the shellfish of EP 0514015A1 are not sexually reproductive. The Office does not have the capability of testing the ability of the shellfish of EP 0514015A1 to reproduce sexually. "When the PTO shows a sound basis for believing that the products of the applicant and the prior art are the same, the applicant has the burden of showing that they are not." In re Spada, 911F.2d 705, 709, 15 USPQ2d 1655, 1658 (Fed. Cir. 1990). Therefore, the prima facie case can be rebutted by evidence showing that the prior art products do not necessarily possess the characteristics of the claimed product. In re Best, 562 F.2d at 1255, 195 USPQ at 433. See the M.P.E.P. 2112.01. As such evidence showing that the shellfish of EP 0514015A1 do not sexually reproduce may be sufficient to overcome the instant rejection.

Accordingly, the rejection is maintained for the reasons of record and as discussed above.

Conclusion

No claim is allowed. Claims 1 and 3-9 appear to be free of the prior art of record but are subject to other rejections.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP

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§ 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner(s) should be directed to Peter Paras, Jr., whose telephone number is 703-308-8340. The examiner can normally be reached Monday-Friday from 8:30 to 4:30 (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at 703-305-4051. Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703) 308-4242 and (703) 305-3014.

Inquiries of a general nature or relating to the status of the application should be directed to Dianiece Jacobs whose telephone number is (703) 305-3388.

Peter Paras, Jr.

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**PETER PARAS
PATENT EXAMINER**

A handwritten signature in cursive script, appearing to read "Peter Paras", is written over the printed name and title.